MAR 2 1 2002

K020733

Summary of Safety and Effectiveness

Prepared January 25, 2002

General Provisions

Submitter of 510(k) Premarket Notification:	Precision Vascular 2405 West Orton Circle West Valley City, UT 84119 Phone: 801.974.1700 Fax: 801.974.1740
Contact Person:	Rick Gaykowski Vice President, Quality Assurance, Regulatory and Clinical Affairs
Device Trade Name:	Not Yet Determined
Device Generic Name:	Infusion Catheter

Predicate Devices

The predicate devices are listed in the table below.

Device	Manufacturer	510(k) Number, Concurrence Date	Product Code
FasTracker-18	Target Therapeutics	K960806, 02 May 1996*	DQO
Rebar-18	Micro Therapeutics	K001966, 20 Jul 2000	KRA

* This information is assumed based on our best, current knowledge.

Classification

Class II, 21 CFR 870.1210, Continuous Flush Catheter

Performance Standards

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use

The PVS 1500 SDS is intended to be used to access tortuous vasculature for infusion of diagnostic, embolic, and therapeutic agents into the distal, peripheral, coronary, and neurovasculature, and for guide wire exchange/support during diagnostic or interventional procedures.

Device Description

The PVS 1500 SDS is a 2.4 F tubular device, 155 cm in length, with a lumen to be used for delivery of contrast, drugs, or embolics. The lumen is constructed from a polymeric material and has an inside diameter of 0.021". The device is coated on the outer diameter with a lubricious coating over the distal segment of the device. Two radiopaque markers are positioned 31 mm apart at the distal tip of the device to aid visualization under fluoroscopy. The proximal end of the device has a standard luer adapter for attachment of accessories and can be used to flush the 1500 SDS. The subject device has the ability to access distal, tortuous vasculature over a guide wire, deliver embolics and agents, and has the ability to be steered like a guide wire as needed.

Technological Characteristics	Technological similarities between the PVS 1500 SDS and predicate devices include the basal tubular design and dimensions, polymeric materials and construction, and hydrophilic coating. In instances where the technological characteristics are different, it has been demonstrated that there are no new questions raised regarding safety or efficacy of the PVS 1500 SDS.
Safety and Performance Tests	Biocompatibility of the PVS 1500 SDS has been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices - Part 1. Test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device. Performance testing of the PVS 1500 SDS was conducted in accordance with ISO 10555-1, Sterile, Single-Use Intravascular Catheters - Part 1. Verification testing for the subject device included dimensional inspection, hub integrity, flow rate measurements, burst strength, tensile strength, guide wire compatibility testing and performance under simulated conditions. Subject product testing is believed to have yielded acceptable results. In addition, torsional strength, torqueability, and corrosion resistance tests also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the PVS 1500 SDS' substantial equivalence to the cited predicate devices.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject PVS 1500 SDS meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2002

Mr. Ned Devine
Program Manager
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K020733
PVS 1500 SDS
Regulation Number: 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: January 25, 2002
Received: March 6, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020733

Device Name: PVS 1500 SDS

Indications for Use:

The PVS 1500 SDS is intended for use in accessing distal peripheral, coronary, and neurovasculature for the sub-selective, controlled, regional delivery of diagnostic, embolic, and therapeutic agents into selected vessels.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020733